IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE HONORABLE BOARD OF PATENT APPEALS AND INTERFERENCES

#19
10/9/03

In re PATENT APPLICATION of:

REITHMULLER-WINZEN, H. *et al.*

Application Serial No: 09/666,146

Filed: September 20, 2000

Group Art Unit: 1617

Examiner: HUI, S.M.R.

Title: METHOD FOR THE THERAPEUTIC MANAGEMENT OF EXTRAUTERINE PROLIFERATION OF ENDOMETRICAL TISSUE, CHRONIC PELVIC PAIN AND FALLOPIAN TUBE OBSTRUCTION

BRIEF ON REPLY

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A. INTRODUCTION

This Reply is to the Examiner's Answer mailed July 29, 2003 in response to the appellant's Brief on Appeal of May 5, 2003.

1. Real Party in Interest

The real party of interest was correctly indicated in the Brief on Appeal and is not in dispute.

2. Related Appeals and Interferences

The related appeals and interferences were correctly indicated in the Brief on Appeal and are not in dispute.

3. Status of Claims

The status of the claims was correctly indicated in the Brief on Appeal. The appellants dispute the examiner's contention that the statement on the status of the claims was incorrect.

To reiterate, claims 1-13 and 28-31 are pending, stand rejected, and are on appeal. The claims on appeal are set forth in the attached Appendix. Claims 1 and 2 are independent, claims 3-13 depend from claim 1, claim 28 depends from claim 2, claim 29 depends from claim 28, claim 30 depends from claim 3, and claim 31 depends from claim 8.

4. Status of Amendments

The status of amendments was correctly indicated in the Brief on Appeal and is not in dispute.

B. SUMMARY OF THE INVENTION

The summary of the invention was correctly indicated in the Brief on Appeal and is not in dispute

C. REJECTIONS AND ISSUES

The rejections and issues were correctly indicated in the Brief on Appeal and is not in dispute.

D. GROUPING OF CLAIMS

The appellants disagree with the examiner's statement that the claim 1-13 and 28-31 stand together and that the appellants' Brief on Appeal does not contain a statement that this grouping does not stand or fall together and reasons in support thereof. On the contrary, the appellants clearly indicated on page 5 of their Brief on Appeal that

> [e]ach claim of this patent application is separately patentable and upon issuance of a patent will be entitled to a separate presumption of validity under 35 U.S.C. §282. For convenience in handling of this appeal, the claims are grouped as follows:
>
> Group I, claims 1, 3-13, 30, and 31; and
> Group II, claims 2, 28, and 29.
>
> Each of Groups I and II will be argued separately in the following arguments. The groups do not stand or fall together. In addition, the claims within each Group do not stand or fall together and are argued separately in the following arguments.

The appellants note further that support for the individual and separate patentability of each claim and arguments rebutting the examiner's rejections were set forth at pages 5-26 of their Brief on Appeal.

E. ARGUMENT

As the examiner has not provided any new reasons for maintaining the rejection of claims 1-13 and 28-31 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Engel *et al.* (U.S. Patent No. 5,663,145) in view of Hodgen (U.S. Patent No. 5,658,884) and Nachtigall *et al.* (Danforth's Obstetrics and Gynecology, Chapter 41, 757-769, 1994), the appellants reiterate the arguments contained in their Brief on Appeal. To avoid redundancy, these arguments are not repeated in this Brief on Reply.

F. CONCLUSION

For at least the reasons discussed above and in the appellants Brief on Appeal, the appellants respectfully submit that claims 1-13 and 28-31 are not unpatentable over Engel *et al.* in view of Hodgen, and Nachtigall *et al.* The appellants respectfully reiterate their request the Honorable Board to reverse the rejection of these claims.

Respectfully submitted,

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G. APPENDIX

Claims 1-13 and 28-31 are pending as follows:

Claim 1. In the method of therapeutic management of extrauterine proliferation of endometrial tissue, chronic pelvic pain and/or fallopian tube obstruction, the improvement consisting of administration of an LHRH antagonist in the form of a short term induction treatment for a period of about 4 to 12 weeks to a patient in need of such treatment, whereby subsequently the administration of the LHRH antagonist is ceased.

Claim 2. In the method of therapeutic management of extrauterine proliferation of endometrial tissue, chronic pelvic pain and/or fallopian tube obstruction, the improvement consisting of administration of an LHRH antagonist in the form of a short term induction treatment for a period of about 4 to 12 weeks to a patient in need of such treatment, wherein the LHRH antagonist is administered in a dosage to achieve the estrogen serum concentration level between about 35 pg/ml and about 80 pg/ml, whereby subsequently the administration of the LHRH antagonist is ceased.

Claim 3. A method according to claim 1 wherein the short-term induction treatment with the LHRH antagonist is followed by administration of a contraceptive.

Claim 4. A method according to claim 1 where the short-term induction treatment with the LHRH antagonist is followed by administration of a non-steroidal anti-rheumatic agent.

Claim 5. A method according to claim 1 wherein the short-term induction treatment with the LHRH antagonist is followed by administration of an analgesic.

Claim 6. A method according to claim 1 wherein the short-term induction treatment with the LHRH antagonist is followed by administration of an androgen other than a 17-alpha-alkyl substituted testosterone.

Claim 7. A method according to claim 1 wherein the short-term induction treatment with the LHRH antagonist is followed by the combined or separate administration of one or more active agents selected from the group consisting of a contraceptive, a non-steroidal anti-rheumatic agent, an analgesic, an androgen other than a 17-alpha-alkyl substituted testosterone or any combinations thereof.

Claim 8. A method according to claim 1 wherein the LHRH antagonist is administered starting in the early to mid follicular phase.

Claim 9. A method according to claim 1 wherein the LHRH antagonist is selected from the group consisting of cetrorelix, teverelix, ganirelix, antide, abarelix and Ac-D-Nal-D-pCl-Phe-D-Pal-Ser-N-Me-Tyr-D-Hci-Nle-Arg-Pro-D-Ala-NH2 LRHR antagonist.

Claim 10. A method according to claim 1 wherein the LHRH antagonist is administered during the short-term induction treatment for about 4 to 12 weeks at a weekly does of about 3 to 10 mg per week.

Claim 11. A method according to claim 1 wherein the LHRH antagonist is administered during the short-term induction treatment for about 4 to 12 weeks at a daily does of about 0.25 mg to 0.5 mg/day.

Claim 12. A method according to claim 1 wherein the LHRH antagonist is administered during the short-term induction treatment for about 4 to 12 weeks at a monthly dose of about 12 to 40 mg per month.

Claim 13. A method according to claim 1 wherein the LHRH antagonist is given for the induction treatment during about 4 to 12 weeks and the treatment is repeated two or three times a year.

Claim 28. A method according to claim 2, wherein said estrogen serum concentration level is between about 45-75 pg/ml.

Claim 29. A method according to claim 28, wherein said estrogen serum concentration level is about 50 to about 75 pg/ml.

Claim 30. A method according to claim 3, wherein said contraceptive is an oral contraceptive.

Claim 31. A method according to claim 8, wherein the LHRH antagonist is administered on cycle day one to three.